UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

MCNEIL-PPC, INC. et al.,	05 Civ. 1321 (WHP)
Plaintiffs,	OPINION AND ORDER
-against-	
PERRIGO COMPANY et al.,	
Defendants.	

WILLIAM H. PAULEY III, District Judge:

McNeil-PPC, Inc. ("McNeil"), Merck & Co., Inc. ("Merck") and Johnson & Johnson · Merck Consumer Pharmaceuticals Co. ("Johnson & Johnson · Merck") (collectively, the "Plaintiffs") bring this action pursuant to the Hatch-Waxman Act, 35 U.S.C. § 271(e)(2), against Perrigo Company, L. Perrigo Company and Perrigo Research & Development Company (collectively, the "Defendants" or "Perrigo"). Plaintiffs accuse Perrigo of infringing U.S. Patent No. 5,817,340 (the "'340 patent") by filing Abbreviated New Drug Application ("ANDA") No. 77-355 with the United States Food and Drug Administration (the "FDA"). Defendants assert that the '340 patent is invalid and that Plaintiffs committed inequitable conduct during the patent's prosecution. This Court conducted a nine-day bench trial in February 2007. Based on the credible evidence, this Court makes the following findings of fact and conclusions of law and invalidates the '340 patent as obvious pursuant to 35 U.S.C. § 103(a).

FINDINGS OF FACT

I. The Parties

McNeil, an operating unit of Johnson & Johnson, is a leading pharmaceutical company that sells over-the-counter pharmaceutical products. (Trial Transcript, dated Feb. 6-28, 2007 ("Tr.") at 7.) Johnson & Johnson · Merck is a joint venture company formed for the purpose of bringing Merck prescription pharmaceutical products over-the-counter. (Tr. at 7-8.) Perrigo is a leading global healthcare supplier. (Defendants' Trial Exhibit ("DX") DDD.)

II. The '340 Patent

The '340 patent claims a solid oral dosage of aluminum hydroxide or magnesium hydroxide (the "antacids") and famotidine. Famotidine is a bitter-tasting guanidinothiazole compound that inhibits acid secretion in the stomach by interfering with histamine receptors in the stomach lining. Aluminum hydroxide and magnesium hydroxide neutralize acid already present in the stomach. When combined in a solid oral dosage, famotidine and antacids are used to treat gastric disorders arising from acid secretion, such as acid indigestion.

McNeil filed the '340 patent application on December 1, 1992 with Edward John Roche ("Roche"), Susan Decoteau ("Decoteau") and Eleanor Freeman ("Freeman") as the named inventors. (DX L; Plaintiffs' Trial Exhibit ("PX") 1.) These inventors, along with McNeil employee John Dubek ("Dubek"), worked together on the Johnson & Johnson · Merck joint venture. The team purportedly discovered that famotidine degrades when exposed to antacids in

a solid dosage form, yielding a therapeutically ineffective product with unknown properties.[1] (PX 1 col. 1, ll. 26-30; col. 2, ll. 41-49; col. 2, ln. 61 – col. 3, ln. 2.) The '340 patent teaches a method for preventing famotidine degradation.

Independent composition claim 1 of the '340 patent recites as follows:

> 1. A solid oral dosage form for the treatment of gastrointestinal disorders comprising a therapeutically effective amount of impermeably coated famotidine granules for the treatment of gastric disorders and pharmacologically acceptable salts thereof; and a therapeutically effective amount of aluminum hydroxide or magnesium hydroxide wherein the oral dosage form has said coated famotidine granules and the aluminum hydroxide or magnesium hydroxide in contact with each other, but separated by said impermeable coating on the famotidine granules which is impermeable to the aluminum hydroxide or magnesium hydroxide.

(PX 1 col. 14, ll. 39-49.) Independent method claim 5 recites as follows:

> 5. A method for manufacturing a solid oral dosage form comprising: a) forming granules containing famotidine for the treatment of gastric disorder; b) coating the granules with a coating impermeable to aluminum hydroxide or magnesium hydroxide to form impermeably coated famotidine granules; c) mixing a therapeutically effective amount of aluminum hydroxide or magnesium hydroxide with a therapeutically effective amount of impermeably coated famotidine granules and pharmaceutically acceptable excipients to form a compression mixture; then d) pressing the compression mixture to form a solid oral dosage form.

(PX 1 col. 15, ln. 6 – col. 16, ln. 2.) The specification details several embodiments of the invention. In the preferred embodiment, granulated famotidine is coated with an impermeable material that protects the famotidine from the antacids. (PX 1 col. 9, ll. 7-12.) The specification provides for two variations on this embodiment. In Examples I and V, the coated famotidine

[1] Before the '340 patent application was filed, McNeil's famotidine supplier, Yamanouchi Pharmaceutical Co., provided McNeil with test results regarding famotidine's stability in an aqueous solution (the "Yamanouchi report"). (PX 114 at 5.) The Yamanouchi report showed that famotidine degrades in water at high and low pH as a result of the hydrolysis reaction. (PX 114 at 5.) McNeil did not disclose the Yamanouchi report to the Examiner.

granules and the antacids are interspersed throughout a single-layer tablet. (PX 1 col. 9, ln. 39 – col. 10, ln. 60; col. 13, ln. 52 – col. 14, ln. 37.) Examples II and III depict two-layer embodiments in which the coated famotidine granules comprise one layer and the antacids comprise the other layer. (PX 1 col. 10, ln. 63 – col. 12, ln. 51.) The specification identifies 23 coatings that are suitable for protecting the famotidine granules. (PX 1 col. 7, ln. 52 – col. 8, ln. 27.) Four of these coatings contain polyvinylpyrrolidone ("PVP").

The Patent Office repeatedly rejected McNeil's original claims, primarily on grounds of obviousness. (DX L, Paper Nos. 5, 9, 16, 20, 24, 29.) On September 18, 1997, Roche submitted a declaration to the Examiner setting forth the results of a test he conducted exposing famotidine to antacids. (DX L, Paper No. 32.) By combining 10mg of uncoated famotidine granules with 200mg of aluminum hydroxide or magnesium hydroxide in a single layer tablet, Roche observed a 25-70% degradation in the famotidine. (DX L, Paper No. 32.) When impermeably coated famotidine granules were substituted for the uncoated granules, approximately 2% degradation occurred. (DX L, Paper No. 32.) The Patent Office deemed the Roche declaration "persuasive as to unexpected results in stability over the prior art for the dosage form tested therein, i.e., coated granule solid oral dosage form containing famotidine and aluminum or magnesium hydroxide." (DX L, Paper No. 33 at 2.) The '340 patent issued on October 6, 1998. (Joint Pretrial Order, dated Jan. 25, 2007 ("JPTO") ¶ VI.A.2.)

Merck holds approved new drug application ("NDA") No. 20-958 for a single-layer tablet containing, inter alia, 10mg of coated famotidine and 165mg of magnesium hydroxide. (JPTO ¶ VI.A.1.) The tablets are marketed over-the-counter under the trade name Pepcid Complete. (JPTO ¶ VI.A.1.) On October 29, 2004, Perrigo filed ANDA No. 77-355 with the FDA requesting permission to market a generic version of Pepcid Complete containing, inter

alia, 10mg of coated famotidine in one layer and 165mg of magnesium hydroxide in a separate layer. (JPTO ¶ VI.A.4, 9.) Perrigo certified that the '340 patent was invalid and would not be infringed by Perrigo's proposed tablet. (JPTO ¶ VI.A.4-5.)

III. Litigation History

On February 3, 2005, Plaintiffs filed this action alleging that the ANDA willfully infringes the '340 patent and requesting attorneys' fees pursuant to 35 U.S.C. § 285. On December 2, 2005, Defendants moved for summary judgment on grounds of non-infringement and invalidity. This Court held a Markman hearing and oral argument concerning Defendants' motion on April 25, 2006. In a Memorandum and Order dated July 27, 2006, this Court construed the '340 patent's claims, denied Defendants' motion for summary judgment on invalidity, and awarded summary judgment to Plaintiffs on the issue of infringement. McNeil-PPC, Inc. v. Perrigo Co., 443 F. Supp. 2d 492 (S.D.N.Y. 2006) ("McNeil I"). The Court's claim construction was as follows: (1) "mixing" in claim 5 was found to mean "combining two or more ingredients into one mass"; (2) "compression mixture" in claim 5 was found to mean "one mass containing two or more ingredients that are compressed into a tablet"; (3) "in contact with" in claim 1 was found to mean "a union or junction of body surfaces, a touching or meeting"; (4) "impermeable" in claims 1 and 5 was found to refer to "a coating material that does not permit the passage of aluminum hydroxide or magnesium hydroxide"; and (5) "impermeably coated famotidine granules" in claims 1 and 5 was found to refer to "famotidine granules that are coated with a material that is impermeable to the aluminum or magnesium hydroxide, using Wurster

coating, rotocoating or another coating process acceptable to a person of ordinary skill in the art."[2] McNeil I, 443 F. Supp. 2d at 503-512.

Defendants moved for reconsideration of the Court's decision granting summary judgment to Plaintiffs on infringement and requested that this Court withdraw and reserve its Markman determination pending trial. By Order dated January 17, 2007, the Court declined to withdraw its Markman rulings. McNeil-PPC, Inc. v. Perrigo Co., No. 05 Civ. 1321 (WHP), 2007 WL 104513 (S.D.N.Y. Jan. 17, 2007) ("McNeil III"). Regarding infringement, the Court noted Defendants' apparent concession at the April 25, 2006 hearing that there were no disputed issues of fact with respect to how Perrigo's tablet is constructed. Nevertheless, affording Defendants the benefit of the doubt, the Court withdrew its summary judgment determination on the issue of infringement and agreed to hear evidence on the issue at trial. McNeil III, 2007 WL 104513, at *1-2.

On September 20, 2006, Perrigo filed its Amended Answer and Counterclaim, alleging that the '340 patent is invalid (1) as obvious under 35 U.S.C. § 103; (2) for failure to name Dubek as an inventor under 35 U.S.C. § 102(f); (3) for failure to disclose the rotogranulation method described in U.S. Patent No. 5,260,072 (the "'072 patent") under the enablement and best mode requirements of 35 U.S.C. § 112; (4) because Plaintiffs failed to disclose the Yamanouchi report during patent prosecution; and (5) because the inclusion of PVP in the patent violates § 112's enablement requirement. Perrigo avers that all but the first of these items also constitutes inequitable conduct. On October 18, 2006, Plaintiffs moved for summary judgment on Defendants' inequitable conduct and related invalidity counterclaims and defenses.

[2] The parties also disputed the meaning of "therapeutically effective amount" in claims 1 and 5. However, the construction of this term was mooted by the Court's construction of the remaining disputed terms. McNeil I, 443 F. Supp. 2d at 509-10.

By Order dated January 12, 2007, the Court granted Plaintiffs' motion with respect to Defendants' '072 rotogranulation method enablement, Yamanouchi report and PVP-related counterclaims and defenses. McNeil-PPC, Inc. v. Perrigo Co., No. 05 Civ. 1321 (WHP), 2007 WL 81918, at *13 (S.D.N.Y. Jan. 12, 2007) ("McNeil II"). The Court denied Plaintiffs' motion with respect to Defendants' '072 rotogranulation best mode and inventorship-related counterclaims and defenses. McNeil II, 2007 WL 81918, at *13.

CONCLUSIONS OF LAW

I. Obviousness

Defendants assert that the '340 patent is invalid as obvious under 35 U.S.C. § 103. This Court agrees.

A. Legal Standard

An issued patent is presumed valid. 35 U.S.C. § 282. Thus, the accused infringer bears the burden of proving invalidity by clear and convincing evidence. 35 U.S.C. § 282; Glaxo Group Ltd. v. Apotex, Inc., 376 F.3d 1339, 1348 (Fed. Cir. 2004); Oakley, Inc. v. Sunglass Hut Int'l, 316 F.3d 1331, 1339 (Fed. Cir. 2003).

A patent claim is invalid if "the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." 35 U.S.C. § 103(a); Merck & Co. v. Teva Pharm. USA, Inc., 395 F.3d 1364, 1372-77 (Fed. Cir. 2005); Ryko Mfg. Co. v. Nu-Star, Inc., 950 F.2d 714, 716 (Fed. Cir. 1991). In determining obviousness, the fact finder must consider the factors set forth in Graham v. John Deere Co., 383 U.S. 1 (1966): (1) the scope and content of the prior art; (2) the

differences between the prior art devices and the claimed invention; (3) the level of ordinary skill in the art;[3] and (4) objective considerations, such as commercial success, long felt but unmet need, and unexpected results. Graham, 383 U.S. at 17-18; see also KSR Int'l Co. v. Teleflex Inc., __ U.S. __, 127 S. Ct. 1727, 2007 WL 1237837, at *6 (2007); Ecolochem, Inc. v. S. Cal. Edison Co., 227 F.3d 1361, 1371 (Fed. Cir. 2000). "While the sequence of these questions might be reordered in any particular case, the factors continue to define the inquiry that controls. If a court . . . conducts this analysis and concludes the claimed subject matter was obvious, the claim is invalid under § 103." KSR, 2007 WL 1237837, at *7.

Until recently, the Federal Circuit had employed an additional test for determining the obviousness of combining prior art references. That inquiry required the party seeking to invalidate a patent to establish "some teaching, suggestion, or motivation to combine the references." In re Rouffet, 149 F.3d 1350, 1355 (Fed. Cir. 1998) (citing In re Geiger, 815 F.2d 686, 688 (Fed. Cir. 1987)); see also ACS Hosp. Sys., Inc. v. Montefiore Hosp., 732 F.2d 1572, 1577 (Fed. Cir. 1984). The "teaching, suggestion or motivation" test was addressed by the Supreme Court in KSR International v. Teleflex Inc. While KSR recognized that the test "captured a helpful insight," the Supreme Court nevertheless cautioned that "[t]he obviousness analysis cannot be confined by a formalistic conception of the words, teaching, suggestion, and motivation." KSR, 2007 WL 1237837, at *14. Courts must avoid a "rigid approach" in determining whether an invention would have been obvious to a skilled artisan. KSR, 2007 WL 1237837, at *12. An "expansive and flexible approach" must instead be applied, and the courts

[3] The Court determined in McNeil I that "one of skill in the art would have a Ph.D in chemistry, organic chemistry, pharmaceutics or pharmaceutical microbiology, or a B.S. or M.S. with several years of work experience in pharmaceutics or pharmaceutical microbiology, or an M.D. with several years of clinical experience in administering H_2 blockers or antacids." McNeil I, 443 F. Supp. 2d at 503.

may utilize "common sense" in addressing a question of obviousness under § 103. KSR, 2007 WL 1237837, at *12, 15; see also DyStar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co., 464 F.3d 1356, 1367-71 (Fed. Cir. 2006); Alza Corp. v. Mylan Labs., Inc., 464 F.3d 1286, 1291 (Fed. Cir. 2006).

"[I]f a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill." KSR, 2007 WL 127837, at *13. "The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." KSR, 2007 WL 1237837, at *12. However, "a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art." KSR, 2007 WL 1237837, at *14; see also Grain Processing Corp. v. Am. Maize-Prods. Co., 840 F.2d 902, 907 (Fed. Cir. 1988) ("In determining obviousness, the inquiry is not whether each element existed in the prior art, but whether the prior art made obvious the invention as a whole for which patentability is claimed" (citation and quotations omitted).). Courts should still "identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does." KSR, 2007 WL 127837, at *14. "Any need or problem known in the field of endeavor at the time of the invention and addressed by the patent can provide a reason for combining the elements in the manner claimed." KSR, 2007 WL 127837, at *15. "[N]either the particular motivation nor the avowed purpose of the patentee controls. What matters is the objective reach of the claim. If the claim extends to what is obvious, it is invalid under § 103." KSR, 2007 WL 1237837, at *15; see also In re Kemps, 97

F.3d 1427, 1430 (Fed. Cir. 1996) ("[T]he motivation in the prior art to combine the references does not have to be identical to that of the applicant to establish obviousness.").

Additionally, the claimed invention as a whole must be compared to the prior art as a whole, Hybritech Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1383 (Fed. Cir. 1986); Hodosh v. Block Drug Co., 786 F.2d 1136, 1143 n.5 (Fed. Cir. 1986), and courts must avoid aggregating pieces of prior art through hindsight which would not have been combined absent the inventors' insight, KSR, 2007 WL 1237837, at *16; Graham, 383 U.S. at 36; Monarch Knitting Mach. Corp. v. Sulzer Morat GmbH, 139 F.3d 877, 880 (Fed. Cir. 1998). As a check against hindsight analysis, the Court must consider "secondary considerations" of nonobviousness. Ruiz v. A.B. Chance Co., 234 F.3d 654, 662-63, 667 (Fed. Cir. 2000); Gambro Lundia AB v. Baxter Healthcare Corp., 110 F.3d 1573, 1579 (Fed. Cir. 1997). These considerations include evidence of commercial success, unexpected results and long felt but unmet need. Dann v. Johnston, 425 U.S. 219, 230 n.4 (1976); Graham, 383 U.S. at 17-18; Syntex (U.S.A.) LLC v. Apotex, Inc., 407 F.3d 1371, 1378 (Fed. Cir. 2005). "Evidence of secondary considerations . . . are but a part of the totality of the evidence that is used to reach the ultimate conclusion of obviousness." Richardson-Vicks Inc. v. Upjohn Co., 122 F.3d 1476, 1483 (Fed. Cir. 1997) (quotations omitted).

B. Scope and Content of the Prior Art

In addressing the question of obviousness, this Court must determine the scope of the prior art. The Davis patent application WO 92/00102 ("Davis") and Wolfe U.S. Patent No. 5,229,137 ("Wolfe") are prior art reciting the combination of uncoated famotidine and magnesium or aluminum hydroxide in a solid oral dosage. (DEX 4; DX F.) The Davis application was based on the purported surprising result that antacids increase the bioavailability

of histamine H_2-receptor antagonists. (DEX 4 at 3.) Thus, Davis "provides the use of an orally administrable pharmaceutical composition comprising a histamine H_2-receptor antagonist and an antacid for the manufacture of a medicament for the treatment of gastric disorders." (DEX 4 at 3.) Famotidine and aluminum hydroxide and magnesium hydroxide were among the H_2-blockers and antacids, respectively, recited by Davis. (DEX 4 at 4, 13-14.) Absent from Davis is any mention of either impermeable coating for the H_2-blockers or famotidine's bitter taste. However, Davis does provide that the medicaments in the tablet formations may be "blended along with conventional tabletting aids, fillers and palatability aids," such as "flavoring agents." (DEX 4 at 7-8.)

Similarly, Wolfe claims a method of "orally administering . . . together or substantially together an antacid in an amount effective to substantially neutralize gastric acid and a histamine H_2-receptor antagonist . . ." (DX F col. 7, ll. 27-30.) The claim "is based upon the unexpected realization that antacids and histamine H_2-receptor antagonists can be effectively administered together or substantially together to achieve continuous relief from pain, discomfort and/or symptoms associated with episodic heartburn . . ." (DX F col. 2, ll. 2-7.) The invention encompasses famotidine, aluminum hydroxide and magnesium hydroxide. (DX F col. 7, ll. 49-52.) Wolfe provides that compositions combining antacids and H_2 blockers may contain "one or more agents such as, for example, sweetening agents, flavoring agents, coloring agents and the like, in order to provide a pharmaceutically elegant and palatable preparation." (DX F col. 4, ll. 40-43.) Like Davis, Wolfe neither states that famotidine tastes bitter nor recites the coating of H_2-blocker granules.

U.S. Patent No. 5,075,114 (the "'114 patent"), which names Roche as the sole inventor, teaches a method for coating granulated medicaments to mask the taste of active

ingredients in chewable tablets. (DX D.) Although ibuprofen is the medicament included in the preferred embodiment of the invention, the '114 specification provides details for the coating of numerous additional medications, including famotidine. (DX D col. 6, ll. 17-18; col. 7, ll. 35-42.) Example III and claims 2, 16 and 19 each identify famotidine as one type of ingredient for which taste-mask coating would be appropriate. (PX D col. 7, ll. 35-42; col. 10, ll. 37-42; col. 12, ll. 4-9, 18-23.) The coatings recited by the '114 patent are a blend of cellulose acetate, cellulose acetate butyrate and hydroxypropylcellulose (DX D col. 2, ll. 21-24), with a preferred coating weight of 7-15% of the total coated granule weight (DX D col. 7, ln. 41). The '340 patent recites the same coating materials at a similar coating weight. (PX 1 col. 7, ln. 58 - col. 8, ln. 27.)

The '072 patent, which lists Roche, Decoteau and Freeman as inventors, claims a method for taste-masking active ingredients by rotogranulation with a preferred particle size ranging from 5-75 microns, a binder ranging from 50-150 microns, and a carrier ranging from 5-75 microns, before application of a coating. (PX 16 col. 1, ll. 14; col. 3, ll. 1-14; col. 9, ln. 39 – col. 10, ln. 10.) Famotidine is the preferred embodiment in the '072 patent and is used in the specification's examples. (PX 16 col. 3, ll. 43-47; col. 8, ln. 4-col. 9, ln. 19.) Thus, the invention "is directed to the discovery of a granulating and coating process for active medicaments which can achieve a better balance between taste masking, dissolution and rate of bioavailability when applied to irregularly shaped raw granules of compositions like famotidine than other previously known coating combinations." (PX 16 col. 2, ll. 46-52.)

Finally, European Patent Application 0,294,933 (the "'933 application") filed on April 5, 1988, is directed to "a solid pharmaceutical dosage form comprising cimetidine and an antacid and to a method for the preparation of such a dosage form." (DX M at 2.) Cimetidine is an H_2 blocker used in the drug Tagamet. (Tr. at 30.) Chewable tablets are among the dosage

forms described in the '933 specification, and the specification provides that "the pronounced bitter taste" of cimetidine may require "a coating agent." (DX M at 3.) Eudragit E 100 is the coating material employed in each of the '933 application's examples. (DX M at 3-8.)

C. Differences Between Claimed Invention and Prior Art

All relevant limitations of the '340 patent—the combination of famotidine and antacids, and use of an impermeable coating—appear in the prior art. Defendants assert that a person of ordinary skill would have incorporated the teachings of the '114 and '072 patents into the composition disclosed in Davis and Wolfe in order to mask famotidine's bitter taste in the combination of famotidine and antacids. Likewise, Defendants contend that a skilled artisan would have arrived at the '340 invention by combining Davis and Wolfe with the '933 application.

The evidence adduced at trial established that famotidine has a bitter taste. (Tr. at 206, 543, 567, 608, 796, 798, 961, 1019, 1075-76.) Plaintiffs contend that the composition at issue is the combination of famotidine and antacid, not famotidine alone, and that Perrigo has failed to show that the combination product has a bitter taste. Yet the NDA Plaintiffs submitted to the FDA for Pepcid Complete states: "Taste masking of famotidine is necessary in [the combination famotidine-antacid product] due to the bitterness of the drug substance." (DX CF at JJ007695, JJ007719; Tr. at 827-29.) Internal McNeil memoranda also indicate Plaintiffs' belief that famotidine has a bitter taste in the combination product. (DX H at JJ008974.) The record evidence therefore establishes that a skilled formulator would have reason to mask the bitter taste

of famotidine even with the addition of antacids.[4]

In the alternative, Plaintiffs contend that other modes of taste-masking are preferable to impermeable coating. Coated granules are "much more" expensive "than simply using flavorants and sweeteners." (Tr. at 1086.) Citing to Celik's testimony, Plaintiffs assert that because of this cost disparity, a skilled formulator would resort to coating only if a bitter taste remained after the addition of flavorants and sweeteners. (Tr. at 1097.) Davis and Wolfe address the issue of the combination product's palatability and, according to Plaintiffs, teach that flavoring and sweetening agents suffice to make a palatable famotidine tablet. In addition to flavoring and sweetening agents, Plaintiffs identify the following inexpensive taste-masking options: (1) granulation alone, without the addition of an impermeable coating; (2) ion exchange resins and cyclodextrins; and (3) altering the solubility of famotidine. (Plaintiffs' Proposed Findings of Fact and Conclusions of Law, dated Mar. 19, 2007 ("PFF") ¶¶ 73-80.) Plaintiffs assert that in light of the alternatives, a person of ordinary skill would not have been motivated to use impermeable coating for taste-masking purposes.

This Court disagrees. Under KSR, "[t]he combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." KSR, 2007 WL 1237837, at *12. The '340 patent does no more than combine the predictable results of Davis and Wolfe with the predictable results of the '072 and '114 patents. Of course, obviousness is not established "merely by demonstrating that each of [an invention's] elements was . . . known in the prior art," because "it can be important to identify a reason that

[4] Relatedly, Plaintiffs assert that "famotidine does not taste especially bad." (PFF ¶ 75.) This statement is not supported by the evidence cited by Plaintiffs. First, they cite the testimony of Dr. Roland Bodmeier, who has never even tasted famotidine. (Tr. at 1564.) They also cite Dr. Metin Celik's testimony, but Celik merely testified that the majority of drugs have a bitter taste and that some drugs are more bitter than others. (Tr. at 1076, 1087.)

would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does." KSR, 2007 WL 1237837, at *14; see also Ruiz, 234 F.3d at 665 ("[T]he notion that combination claims can be declared invalid merely upon finding similar elements in separate prior patents would necessarily destroy virtually all patents and cannot be the law under the statute, § 103" (citation and quotations omitted).). But pre-KSR precedent refutes Plaintiffs' theory of non-obviousness, which is that the costs of the coating process would have dissuaded a skilled formulator from combining the references. "[T]he fact that the [prior art] would not be combined by businessmen for economic reasons is not the same as saying that it could not be done because skilled persons in the art felt that there was some technological incompatibility that prevented their combination. Only the latter fact is telling on the issue of nonobviousness." Orthopedic Equip. Co. v. United States, 702 F.2d 1005, 1013 (Fed. Cir. 1983).

KSR casts doubt on the continuing validity of Federal Circuit precedent on the issue of obviousness. The Supreme Court did suggest, however, that some Federal Circuit caselaw may have appropriately applied the broad conception of the teaching, suggestion or motivation test that the Supreme Court has endorsed. KSR, 2007 WL 1237837, at *16. This Court perceives no conflict between KSR and the portion of Orthopedic Equipment cited above.

Even if Plaintiffs advanced a legally cognizable theory, the evidence establishes that a skilled artisan in 1991 or 1992 would have been motivated to use impermeable coating to improve the palatability of a chewable tablet comprised of coated famotidine and antacids. In an internal Johnson & Johnson · Merck memorandum dated August 1, 1991, Roche discusses his progress in developing a famotidine-antacid tablet. (DX H at JJ008974.) The memorandum addresses whether an impermeable coating would be sufficient to prevent interaction between

famotidine and the antacids. In the course of advocating the use of such a coating, Roche stated: "It is expected that coated Famotidine would be used in these products anyway to achieve taste masking." (DX H at JJ008974.) This admission undermines Plaintiffs' assertion that the use of an impermeable coating for taste-masking purposes would not have been obvious to a skilled formulator. Roche was a person of ordinary skill, and the additional costs associated with the coating process would not have dissuaded him from applying an impermeable taste-mask coating to the combination product.[5] Based on this evidence, "it appears quite feasible both economically and technologically, to combine the [prior art] to arrive at the claims in suit." Orthopedic Equip., 705 F.2d at 1013.

Plaintiffs urge this Court to ignore Roche's contemporaneous statement based on the following language in KSR: "The question is not whether the combination was obvious to the patentee but whether the combination was obvious to a person with ordinary skill in the art." KSR, 2007 WL 1237837 at *15. This argument misinterprets KSR. The quoted language means only that an invention may be obvious based on the combination of prior references even though the invention and the references do not address the same problem. KSR, 2007 WL 1237837, at *15 (holding that "any need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed"). The notion that contemporaneous admissions by the skilled inventor of the patent in suit must be ignored finds no support in any of the cited precedents, let alone KSR. "Common sense" dictates that if these admissions raise an inference of obviousness, then the patent is invalid under § 103. KSR, 2007 WL 1237837, at *15.

[5] For this reason, the Court also rejects Plaintiffs' argument that even if a formulator had decided to use coated granules, he would not necessarily have selected an impermeable material for the coating. (PFF ¶ 81.) Roche clearly anticipated using an impermeable coating to mask famotidine's taste.

Likewise, Plaintiffs' reliance on Winner Int'l Royalty Corp. v. Wang, 202 F.3d 1340 (Fed. Cir. 2000) is misplaced. In Winner, the Federal Circuit upheld the district court's rejection of the petitioner's obviousness argument, relying in part on a lack of motivation to combine the prior art. Winner, 202 F.3d at 1349. Assuming the holding in Winner survives KSR, it actually supports a finding of obviousness in this case. Winner states as follows:

> The fact that the motivating benefit comes at the expense of another benefit . . . should not nullify its use as a basis to modify the disclosure of one reference with the teachings of another. Instead, the benefits, both lost and gained, should be weighed against one another.

Winner, 202 F.3d at 1349 n.8. Roche conceded in 1991 that the "motivating benefit" of a taste-mask coating was not "nullified" by the costs of the coating process. (DX H at JJ008974.) A person of ordinary skill would appreciate the "desirability" of using coated famotidine for taste-masking purposes in the combination famotidine-antacid blend. Winner, 202 F.3d at 1349.

The obviousness of the '340 patent is underscored by the Pepcid Complete NDA, which states: "Taste masking of famotidine is necessary in a chewable tablet due to the bitterness of the drug substance. [The combination product] includes the use of coated famotidine granulation . . ." (DX CF at JJ007695, JJ007719; see also Tr. at 827-28.) Impermeable coating is the only taste-masking process mentioned in the excerpts of the NDA that were submitted by the parties. Plaintiffs argue that the famotidine in Pepcid Complete was coated to prevent interaction with the antacids, and that any taste-masking benefit was incidental. However, it is telling that that the NDA makes no mention of Pepcid Complete's sweetening and flavoring agents in addressing famotidine's bitterness. Indeed, coated famotidine is the only taste-masking option disclosed in any reference that specifically identifies famotidine's bitter taste.

Prior to launching Pepcid Complete, McNeil also developed a single active ingredient famotidine tablet marketed as Pepcid AC chewable. (Tr. at 541-43.) Plaintiffs employed coated famotidine granules in this tablet for the purpose of masking the taste of famotidine. (Tr. at 543-44.) Decoteau, who was involved in the development of the famotidine tablet, conceded at trial that a coating was chosen over sweeteners and flavoring agents because "attempts to use flavorants and other materials to hide the taste of the famotidine were unsuccessful." (Tr. at 543.) Decoteau agreed with Defendants that "the coating was selected because of its superior taste masking properties over other technologies that might be available to taste mask." (Tr. at 544.) Thus, McNeil's previous efforts to use sweeteners and flavors to hide famotidine's bitter taste had proven unsuccessful. (Tr. at 543.) Plaintiffs argue that the bitterness of famotidine is diluted by the other ingredients in the larger famtodine-antacid combination, thereby mitigating the taste-masking problem. This Court does not credit Plaintiffs' assertion. To the contrary, the evidence indicates that Plaintiffs themselves considered impermeable coating necessary for the combination product.[6] (DX H at JJ008974.)

For these reasons, a person of ordinary skill would have ample reason to combine Davis and Wolfe with the '114 and the '072 patents. It also would have been obvious to combine Davis and Wolfe with the '933 application. The '933 specification states:

> With chewable [combination cimetidine/antacid] tablets, the pronounced bitter taste of cimetidine means that in practice it is necessary to provide a means of masking the bitter taste. One means of masking the bitter taste is to coat the cimetidine with a coating agent in an amount effective to mask the bitter taste but

[6] As previously noted by this Court, both the '072 and '114 patents teach that flavoring agents can "overpower" the bitter taste of famotidine "[i]n some cases," such as within children's aspirin "where the dosage [of famotidine] is small enough." (PX 16 col. 1 ll. 52-60; DX D col. 1, ll. 49-55.) That is not the case here. The '072 patent teaches the use of 10 mg of famotidine, the same amount taught by the'340 patent. (PX 16 col. 8, ln. 62 – col. 9, ln. 18; PX 1 col. 9, ln. 39 – col. 10, ln. 60.)

> which does not significantly affect the bioavailability of the cimetidine.

(DX M at p. 3, ll. 7-10.) Cimetidine, like famotidine, is an H_2 blocker. (Tr. at 30.) A skilled formulator would have understood the utility of replacing cimetidine with famotidine in the '933 invention. See Richardson-Vicks, 122 F.3d at 1483-84 (combination of medicaments in a single tablet found obvious when similar combinations were disclosed in the prior art).

Plaintiffs contend that Eudragit is used in the '933 patent to granulate but not to coat the cimetidine, because the examples in the specification employ Eudragit during the granulation process. (Tr. at 339-45.) However, Eudragit is listed in the '340 patent as a "suitable coating" (PX 1 col. 8, ln. 10), and McNeil itself referred to the use of Eudragit as a "coating" in describing the '933 patent to the '340 Examiner (DX L, Paper No. 18 at 000149). Plaintiffs do not dispute that Eudragit may be employed as both a granulation binder and as a coating agent. Nor do they explain why the '933 application refers to Eudragit as a "coating" if it does not teach the coating of cimetidine. Even if the '933 application's reference to Eudragit as a coating were somehow unintentional, that would not bar Eudragit's use for that purpose. A formulator could easily read the '933 application to mean what it says—namely, that Eudragit is to be used as a coating.

D. Secondary Considerations

Plaintiffs contend that Defendants' showing of obviousness is negated by the commercial success of Pepcid Complete and the supposedly unexpected results on which the '340 patent was based. This Court disagrees.

1. Commercial Success

"Commercial success is relevant [to obviousness] because the law presumes an idea would successfully have been brought to market sooner, in response to market forces, had

the idea been obvious to persons skilled in the art." Merck, 395 F.3d at 1376. Thus, the law deems evidence of (1) commercial success, and (2) a causal relation or nexus between an invention and commercial success of a product embodying that invention, probative of whether an invention was non-obvious. Merck, 395 F.3d at 1376; J.T. Eaton & Co. v. Atlantic Paste & Glue Co., 106 F.3d 1563, 1571 (Fed. Cir. 1997); In re Gpac Inc., 57 F.3d 1573, 1580 (Fed. Cir. 1995); Demaco Corp. v. F. Von Langsdorff Licensing Ltd., 851 F.2d 1387, 1392 (Fed. Cir. 1988). Commercial success is "usually shown by significant sales in a relevant market." J.T. Eaton, 106 F.3d at 1571. "[T]he secondary consideration of commercial success exists largely to provide a means for patentees to show in close cases that subject matter that appears obvious is in law unobvious because a high degree of commercial success permits the inference that others have tried and failed to reach a solution." Syntex, 407 F.3d at 1383 (citing Merck, 395 F.3d at 1376). Although "[i]n some cases [secondary considerations are] the most probative of obviousness . . . [t]he existence of such evidence . . . does not control the obviousness determination." Richardson-Vicks, 122 F.3d at 1483 (internal citations omitted).

Pepcid Complete appears to have enjoyed some measure of commercial success. Nevertheless, Plaintiffs have failed to establish a nexus between the '340 patent and the Pepcid Complete product. First, prior the introduction of Pepcid Complete, Plaintiffs had successfully marketed the Pepcid brand through a variety of products, including Pepcid AC. (Tr. at 37-38.) The evidence introduced at trial shows that McNeil spent over $90 million per year on advertising to promote the Pepcid brand. (PX 167 at 2; Tr. at 42.) Pepcid's overall brand strength weakens the inference that Pepcid Complete's commercial success arose from incorporation of the '340 invention. Pentec, Inc. v. Graphic Controls Corp., 776 F.2d 309, 316 (Fed. Cir. 1985) ("Because GC was clearly the market leader well before the introduction of the

[invention to the marketplace], its sales figures cannot be given controlling weight in determining the effect of commercial success in this case on the question of obviousness."); see also Schwinn Bicycle Co. v. Goodyear Tire & Rubber Co., 444 F.2d 295, 300 (9th Cir. 1970) (patent found obvious despite commercial success where "Schwinn [w]as a national leader in the design and manufacture of bicycles").

Second, the advertising launch for Pepcid Complete was substantial; McNeil diverted more than one third of its total Pepcid brand advertising dollars to Pepcid Complete. (DX GG.) The inference of non-obviousness arising from commercial success is weakened where the patentee's "promotional campaign contributed to the patented [product's] commercial success." Pentec, Inc., 776 F.2d at 316.

Third, Plaintiffs' marketing plan involved switching users from Pepcid AC to Pepcid Complete. (DX II at 3; Tr. at 51.) The plan was successful, as Pepcid Complete cannibalized a large number of Pepcid AC sales. (Tr. at 53, 65.) Pepcid AC chewable tablets were eventually taken off the market, leaving Pepcid Complete as the only remaining chewable Pepcid product. (Tr. at 59.) This raises an inference that Pepcid Complete's success is derived at least in part from the cannibalization of Pepcid AC.

Finally, Pepcid Complete is covered by at least three patents—the '340 patent, the 5,229,137 patent, and the 5,989,588 patent. (DX BE.) This makes it difficult to attribute whatever commercial success Pepcid Complete may enjoy to any one of the three patents. For these reasons, Plaintiffs have not made a sufficient showing that Pepcid Complete's success is

attributable to the patent in suit.[7] See Dystar, 464 F.3d at 1371 (patent found obvious despite commercial success); Gpac, Inc., 57 F.3d at 1580-81 (same); Pentec, Inc., 776 F.2d at 315-17 (same).

2. Unexpected Results

"Unexpected results may be sufficient to rebut a prima facie case of obviousness." Kao Corp. v. Unilever U.S., Inc., 441 F.3d 963, 970 (Fed. Cir. 2006); see also In re De Blauwe, 736 F.2d 699, 706 n.8 (Fed. Cir. 1984) ("A proper showing of unexpected results will rebut a prima facie case of obviousness."). "The basic principle behind this [rule] is straightforward—that which would have been surprising to a person of ordinary skill in a particular art would not have been obvious." In re Mayne, 104 F.3d 1339, 1343 (Fed. Cir. 1997).

Plaintiffs assert that the Roche declaration disclosed the unexpected result that famotidine degrades 25-70% when exposed to antacids in solid form. Assuming that the famotidine degradation observed by Roche was indeed unexpected—Defendants offer evidence that it was not (Defendants Proposed Findings of Fact, dated Mar. 19, 2007 ¶¶ 49-65)—the Roche declaration is insufficient to overcome the other evidence of obviousness in this case. Pfizer, Inc. v. Apotex, Inc., 480 F.3d 1348, 1372 (Fed. Cir. 2007) ("[W]e hold that even if Pfizer showed that amlodipine besylate exhibits unexpectedly superior results, this secondary consideration does not overcome the strong showing of obviousness in this case."). The Court notes that the patent in suit is rendered obvious for reasons entirely unrelated to the medicament's instability, and the inventor himself declared that impermeable coating would be

[7] For similar reasons, Plaintiffs have not established that Pepcid Complete fulfilled an unmet need in the marketplace. Plaintiffs' own marketing study prior to the launch of Pepcid Complete concluded that "the idea of a combination antacid and acid controller is not perceived to fulfill an unmet need." (DX BN.)

used for taste-masking purposes regardless of whether famotidine interacted with the antacids. The invention was therefore obvious even if the level of interaction was surprising.

In sum, "[t]he unexpected results and commercial success of the claimed invention, [even if] supported by substantial evidence, do not overcome the clear and convincing evidence that the subject matter sought to be patented is obvious." Richardson-Vicks, 122 F.3d at 1484; see also Leapfrog Enters., Inc. v. Fisher-Price, Inc., __ F.3d __, 2007 WL 1345333, at *5 (Fed. Cir. 2007) (affirming invalidation of patent when the "district court explicitly stated in its opinion that Leapfrog had provided substantial evidence of commercial success, praise, and long-felt need, but that, given the strength of the prima facie obviousness showing, the evidence on secondary considerations was inadequate to overcome a final conclusion that claim 25 would have been obvious"). Because the '340 patent is invalid under § 103, this Court need not consider Perrigo's remaining invalidity arguments. McNeil's contention that Perrigo's ANDA infringes the '340 patent is also rendered moot by the invalidity of the patent.

VI. Attorneys Fees

Perrigo seeks attorneys fees under 35 U.S.C. § 285, contending that McNeil committed inequitable conduct by (1) failing to disclose the best mode of practicing the '340 patent, and (2) excluding Dubek from the '340 patent's named inventors. For the following reasons, Perrigo's application is denied.

A. Applicable Standards

In "exceptional cases," the Court may award reasonable attorneys fees to the party prevailing in a patent infringement action. 35 U.S.C. § 285. To determine whether a case is

exceptional, a trial court must look at the totality of the circumstances. Yamanouchi Pharm. Co. v. Danbury Pharmacal, Inc., 231 F.3d 1339, 1347 (Fed. Cir. 2000).

"Inequitable conduct is a . . . defense to patent infringement and, either alone or in conjunction with trial conduct, may constitute the basis for an award of attorney fees under 35 U.S.C. § 285." A.B. Chance Co. v. RTE Corp., 854 F.2d 1307, 1312 (Fed. Cir. 1988). "Inequitable conduct occurs when a patent applicant breaches his or her duty of candor and good faith to the PTO." Novo Nordisk Pharm., Inc. v. Bio-Technology Gen. Corp., 424 F.3d 1347, 1359 (Fed. Cir. 2005); see also Bruno Indep. Living Aids, Inc. v. Acorn Mobility Servs., Ltd., 394 F.3d 1348, 1351 (Fed. Cir. 2005). Inequitable conduct may include an "affirmative misrepresentation of a material fact, failure to disclose material information, or submission of false material information, coupled with an intent to deceive." Molins PLC v. Textron, Inc., 48 F.3d 1172, 1178 (Fed. Cir. 1995). Thus, the inequitable conduct analysis is performed in two steps: "first, a determination of whether the [conduct] meets a threshold level of materiality and intent to mislead, and second, a weighing of the materiality and intent in light of all the circumstances to determine whether the applicant's conduct is so culpable that the patent should be held unenforceable." Purdue Pharma L.P. v. Boehringer Ingelheim GmbH, 237 F.3d 1359, 1366 (Fed. Cir. 2001) (internal quotations and alterations omitted).

Material references may include any information that a reasonable patent examiner would find important in deciding whether the proposed claims are patentable. Digital Control Inc. v. Charles Mach. Works, 437 F.3d 1309, 1314-16 (Fed. Cir. 2006); Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc., 326 F.3d 1226, 1234, 1236 (Fed. Cir. 2003). Information that is merely cumulative of references already before the examiner is not material. Mentor H/S, Inc. v. Med. Device Alliance, Inc., 244 F.3d 1365, 1378 (Fed. Cir. 2001).

"Intent need not, and rarely can, be proven by direct evidence." Merck & Co. v. Danbury Pharmacal, Inc., 873 F.2d 1418, 1422 (Fed. Cir. 1989). "Rather, in the absence of a credible explanation, intent to deceive is generally inferred from the facts and circumstances surrounding a knowing failure to disclose material information." Bruno Indep., 394 F.3d at 1354 (citing Paragon Podiatry Lab. v. KLM Lab., 984 F.2d 1182, 1193 (Fed. Cir. 1993)). An inference of intent to deceive is based on the totality of the circumstances, including the nature of the conduct and the presence or absence of good faith. Li Second Family L.P. v. Toshiba Corp., 231 F.3d 1373, 1379-80 (Fed. Cir. 2000). Gross negligence alone is insufficient to establish intent. Kingsdown Med. Consultants, Ltd. v. Hollister, Inc., 863 F.2d 867, 876 (Fed. Cir. 1988); see also Baxter Int'l, Inc. v. McGaw, Inc., 149 F.3d 1321, 1329 (Fed. Cir. 1998).

"As a general principle, materiality and intent are balanced—a lesser quantum of evidence of intent is necessary when the omission or misrepresentation is highly material, and vice versa." Amgen Inc. v. Hoechst Marion Roussel, Inc., 314 F.3d 1313, 1358 (Fed. Cir. 2003); see also Li Second Family, 231 F.3d at 1378; Digital Control, 437 F.3d at 1315-16. "At the same time, however, there must be some threshold showing of intent to be balanced; [courts] will not find inequitable conduct on an evidentiary record that is completely devoid of evidence of the patentee's intent to deceive the PTO." Amgen, 314 F.3d at 1358. Finally, "[w]hen both materiality and deceptive intent have been established by clear and convincing evidence, decision of the ultimate issue of inequitable conduct is within the discretion of the district court." Norian Corp. v. Stryker Corp., 363 F.3d 1321, 1331 (Fed. Cir. 2004).

B. Best Mode

Defendants contend that the inventors of the '340 patent considered the rotogranulation method claimed in the '072 patent, i.e., using a small particle size, binder and

carrier, to be the best mode for preparing coated famotidine granules. According to Defendants, McNeil committed inequitable conduct by omitting the '072 rotogranulation method from the '340 patent.

A patent's specification must "set forth the best mode contemplated by the inventor of carrying out his invention." 35 U.S.C. § 112. Thus, if an inventor has a way of practicing the invention that is better than all other ways, it must be disclosed in the patent specification. See N. Telecom Ltd. v. Samsung Elecs. Co., 215 F.3d 1281, 1286 (Fed. Cir. 2000). Assessing compliance with the best mode requirement requires a two-pronged factual inquiry. First, it must be determined whether the inventor had a best mode of practicing the invention when the patent application was filed. Nobelpharma AB v. Implant Innovations, Inc., 141 F.3d 1059, 1064 (Fed. Cir. 1998); United States Gypsum Co. v. Nat'l Gypsum Co., 74 F.3d 1209, 1212 (Fed. Cir. 1996). This is a subjective inquiry, which focuses on "the inventor's state of mind at the time of filing." Eli Lilly & Co. v. Barr Labs., Inc., 251 F.3d 955, 963 (Fed. Cir. 2001). Second, it must be determined whether the best mode was disclosed in sufficient detail to allow a person of ordinary skill in the art to practice it. Nobelpharma, 141 F.3d at 1064; United States Gypsum, 74 F.3d at 1212. This inquiry is objective and looks to the "scope of the claimed invention and the level of skill in the art." Eli Lilly, 251 F.3d at 963.

Perrigo has failed to show that the alleged best mode violation was material, or that Plaintiffs acted with an intent to conceal the best mode in prosecuting the '340 patent. Prior to filing the '340 patent, Plaintiffs published the '072 rotogranulation method with a variety of international patent offices. In particular, on March 4, 1992, McNeil's European Patent Office publication 0 473 431 was disclosed to the public. (PX 295.) This publication employed the same language later used in the '072 patent regarding a rotogranulation method with a small

particle size, binder and carrier. (PX 295 at 1, 3-4.) Identical language is found in patent applications published by McNeil in Australia and Canada. (PX 232 at 1, 5, 8; PX 292 at 1, 5, 8.)

"[W]hether the inventor concealed [the best mode] is a function of . . . how one skilled in the art would have understood his disclosure." Chemcast Corp. v. ARCO Indus. Corp., 913 F.2d 923, 927 (Fed. Cir. 1990). As a result, there can be no best mode violation where a person of ordinary skill would have known the purported best mode through the scientific literature. Ajinomoto Co. v. Archer-Daniels-Midland Co., 228 F.3d 1338, 1346 (Fed. Cir. 2000). Although mere publication of a patent application in a foreign country is not necessarily sufficient to notify a person skilled in the art of the invention, see In re Howarth, 654 F.2d 103, 107 (C.C.P.A. 1981), the evidence at trial established that during the relevant time period, scientists and attorneys routinely searched EPO publications using the databases of various abstracting services (Tr. at 167-68, 685-86, 903, 906). EPO publications were considered one of the best informational sources for technological developments. (Tr. at 167, 903.) Indeed, even Perrigo has referenced EPO publications in its patents. (PX 400 col. 1, ll. 23-32.) Perrigo's best mode allegations are weakened by the availability of the '072 rotogranulation method through the EPO and other patent offices. Ajinomoto Co., 228 F.3d at 1346. That McNeil published the '072 rotogranulation method prior to filing the '340 application also undermines any inference that McNeil intentionally concealed the method from the '340 Examiner.[8]

[8] Perrigo urges this Court to consider Plaintiffs' inequitable conduct in prior litigations in assessing whether there was intent to deceive the '340 Examiner. The Court declines to do so. For the evidence to be admissible under Fed. R. Evid. 404(b), there must be a "close relation" between the prior conduct and the conduct alleged in the case at bar. Semiconductor Energy Lab. Co. v. Samsung Elec. Co., 4 F. Supp. 2d 477, 487 n.16 (E.D. Va. 1998); see also Procter & Gamble Co. v. Nabisco Brands, Inc., 697 F. Supp. 1360, 1366 (D. Del. 1988). Perrigo has failed to establish such a nexus.

This conclusion is bolstered by several features of the '340 patent. First, the purpose of using the '072 method was to achieve spherical famotidine granules to which an impermeable coating can be easily applied. Yet the '340 specification discloses a preference for spherical granules (PX 1, col. 7, ll. 38-40), and Defendants' granulation expert conceded at trial that an ordinary skilled artisan in 1991 or 1992 would have been able to create spherical famotidine granules without reference to the '072 patent (Tr. at 1220-22). It is well settled that "an inventor need only disclose information about the best mode that would not have been apparent to one of ordinary skill in the art." Young Dental Mfg. Co. v. Q3 Special Prods., Inc., 112 F.3d 1137, 1144 (Fed. Cir. 1997); see also High Concrete Structures, Inc. v. New Enter. Stone & Lime Co., 377 F.3d 1379, 1383 (Fed. Cir. 2004) ("The best mode requirement of § 112 is not violated by unintentional omission of information that would be readily known to persons in the field of the invention."). Although there is a suggestion in the '072 specification and elsewhere that using a carrier of 5-75 microns provides unique advantages in creating spherical granules, the evidence before this Court is inadequate to demonstrate why this is so. Second, the '340 patent did disclose rotogranulation using, inter alia, a confectioners sugar carrier, which has a fine particle size between 5 and 75 microns. (PX 1, col. 8, ll. 60-64; Tr. at 159.) Under these circumstances, Defendants have failed to establish the quantum of materiality and intent required to substantiate an inequitable conduct claim.

C. Inventorship

Defendants also allege inequitable conduct based on Plaintiffs' failure to name Dubek as an inventor of the '340 patent. A patented invention may be the work of two or more joint inventors. 35 U.S.C. § 116. To qualify as a joint inventor, one must "(1) contribute in some significant manner to the conception or reduction to practice of the invention, (2) make a

contribution to the claimed invention that is not insignificant in quality, when that contribution is measured against the dimension of the full invention, and (3) do more than merely explain to the real inventors well-known concepts and/or the current state of the art." Pannu v. Iolab Corp., 155 F.3d 1344, 1351 (Fed. Cir. 1998); see also Acromed Corp. v. Sofamor Danek Group, 253 F.3d 1371, 1379 (Fed. Cir. 2001). "[O]ne does not qualify as a joint inventor merely by assisting the actual inventor after conception of the claimed invention." Ethicon, Inc. v. United States Surgical Corp., 135 F.3d 1456, 1460 (Fed. Cir. 1998). "Conception is the formation in the mind of the inventor, of a definite and permanent idea of the complete and operative invention, as it is hereafter to be applied in practice." Ethicon, Inc., 135 F.3d at 1460 (quoting Hybritech, Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1376 (Fed. Cir. 1986)). "An idea is sufficiently 'definite and permanent' when 'only ordinary skill would be necessary to reduce the invention to practice, without extensive research or experimentation.'" Ethicon, Inc., 135 F.3d at 1460 (quoting Burroughs Wellcome Co. v. Barr Labs., Inc., 40 F.3d 1223, 1228 (Fed. Cir. 1994)).

Plaintiffs did not commit inequitable conduct by excluding Dubek from the '340 patent's inventorship. In his trial testimony, Dubek never claimed to be an inventor of the '340 patent or to have contributed to the conception of the invention, and Defendants advance no reason to question Dubek's veracity. "When an alleged omitted co-inventor does not claim to be such, it can hardly be inequitable conduct not to identify that person to the PTO as an inventor." Pro-Mold & Tool Co. v. Great Lakes Plastics, Inc., 75 F.3d 1568, 1576 (Fed. Cir. 1996).

Even had Dubek contributed to the conception of the patent, Defendants have failed to establish Plaintiffs' intent. Defendants speculate that Dubek was denied inventorship status because his inclusion as an author would have endangered the '340 patent application. According to Defendants, disclosing the '072 application to the '340 Examiner might have

prompted the Examiner to reject the '340 patent because coating famotidine for taste-masking purposes would have been obvious to a skilled formulator. In the prosecution of a patent, a prior invention is excluded from the definition of prior art if it was authored by the inventors named in the patent application. 35 U.S.C. § 102. Thus, so long as Decoteau, Freeman and Roche authored the '340 patent, the '072 application was excluded from the prior art, and disclosure of the '072 application to the '340 Examiner was unnecessary.

The record evidence does not substantiate this theory and, indeed, it is undisputed that Plaintiffs disclosed the '114 patent to the Examiner. (DX D; DX L, Paper No. 14 at 118.) The '114 patent, like the '072 patent, reveals the use of impermeable coating to mask the taste of famotidine. The evidence does not support an inference that Dubek was intentionally withheld from the '340 patent's inventorship.[9]

D. 35 U.S.C. § 285

Defendants' request for attorneys fees is predicated on the allegation that Plaintiffs' inequitable conduct renders this case "exceptional" under 35 U.S.C. § 285. Because Defendants have failed to show inequitable conduct, their request for attorneys fees is denied. However, even if Plaintiffs had committed inequitable conduct, the Court would still decline to award fees.

A Court must exercise discretion in determining whether an award of attorneys fees is warranted. See Enzo Biochem, Inc. v. Calgene, Inc., 188 F.3d 1362, 1370 (Fed. Cir. 1999); see also Graco, Inc. v. Binks Mfg. Co., 60 F.3d 785, 794-95 (Fed. Cir. 1995) ("A finding

[9] Perrigo also raises the defense that McNeil violated § 102(f) by naming Freeman as an inventor of the '340 patent. Perrigo waived this defense by asserting in the Joint Pretrial Order that the only inventorship issue to be tried was whether the patent failed "to name one of the true inventors of the subject matter claimed." (JPTO at 3.) See Satnick v. Amtrak, No. 03 Civ. 4896 (RKE), 2005 WL 236493, at *2 (S.D.N.Y. Feb. 1, 2005) (finding an argument to be waived based on concession in the joint pretrial order).

by a court that a case is exceptional is a factual determination . . . whereas the decision to award fees is discretionary."). A number of factors determine whether attorneys fees are appropriate, including the "closeness of the case, tactics of counsel, the conduct of the parties and any other factors that may contribute to a fairer allocation of the burdens of litigation as between winner and loser." J.P. Stevens Co. v. Lex Tex Ltd., 822 F.2d 1047, 1051 (Fed. Cir. 1987) (quoting S.C. Johnson & Son, Inc. v. Carter-Wallace, Inc., 781 F.2d 198, 201 (Fed. Cir. 1986)). Thus, "[a]ttorney fees are not to be routinely assessed against a losing party in litigation in order to avoid penalizing a party 'for merely defending or prosecuting a lawsuit,' and are awarded to avoid a gross injustice." Revlon, Inc. v. Carson Prods. Co., 803 F.2d 676, 679 (Fed. Cir. 1986) (quoting Fleischmann Distilling Corp. v. Maier Brewing Co., 386 U.S. 714, 718 (1967)).

Inequitable conduct in this case could be found, hypothetically, only by a "close margin." J.P. Stevens Co., 822 F.2d at 1051; see also Elk Corp. v. GAF Bldg. Materials Corp., No. 94 Civ. 294, 2000 WL 265765, at *2 (N.D. Tex. Mar. 7, 2000) (denying application for fees under § 285 where "whether Elk engaged in inequitable conduct itself was "a close question"). McNeil's conduct before the Examiner was not so "egregious or lacking in good faith as to afford a basis for finding this to be an 'exceptional' case," and Plaintiffs' engaged in no litigation misconduct before this Court. Oshkosh Truck Corp. v. Lockheed Missiles & Space Co., 678 F. Supp. 809, 812 (N.D. Cal. 1987). Therefore, this case is not exceptional under 35 U.S.C. § 285 and an award of attorneys fees is not warranted.

CONCLUSION

Accordingly, this Court concludes that (1) the '340 patent is invalid under 35 U.S.C. § 103; and (2) this case is not exceptional under 35 U.S.C. § 285. The foregoing constitutes this Court's findings of fact and conclusions of law as required by Rule 52 of the Federal Rules of Civil Procedure. The parties are directed to submit a final judgment consistent with this Opinion and Order within seven business days.

Dated: June 5, 2007
New York, New York

SO ORDERED:

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